JAN 1 3 2003

510(k) Summary
Impulse™ Adjusting Instrument; also known as (aka)
Neuromechanical Adjusting Instrument™; aka
CBP® Adjusting Instrument

Manufacturer:	Neuromechanical Innovations, LLC 11011 S. 48th St., Suite 205 Phoenix, AZ 85044
Contact:	Christopher J. Colloca, D.C. Phone: 480-785-8442 Fax: 480-893-2412 Email: cjcolloca@neuromechanical.com
Contract Manufacturer:	FA Green 9742 352nd Ave., S.E. Snoqualmie, WA 98065
Contract Manufacturer Contact:	Jeff Green Telephone: (425) 888-0007 Facsimile: (425) 888-0675 Email: sensors@centurytel.net
Trade Name(s):	Impulse™ Adjusting Instrument aka (also known as) Neuromechanical Adjusting Instrument™ aka (also known as) CBP® Adjusting Instrument
Common or Usual Name:	Chiropractic Adjusting Instrument
Classification Name:	Manipulator, Plunger-like Joint
Predicate Devices for Substantial Equivalence:	K010851 – Harrison Hand Held Adjusting Instrument K001476 – Torque Specific Cervical Adjusting Instrument K930431 – Arthrostim K003185 – Full Spectrum Activator III K973506 – Activator II Adjusting Instrument
Establishment Registration #:	Applied for herein.
Classification:	Unclassified
Panel:	Physical Medicine
Performance Standards:	None known established

Device Description & Specifications:
Impulse™ (aka Neuromechanical™, aka CBP®) Adjusting Instrument is a hand-held electromechanical chiropractic adjusting instrument intended to be used for chiropractic adjustment or manipulation/mobilization of the joints of the spine and extremities. The device is only intended for use from a health care professional licensed by the law of the state that he or she practices.

The instrument's shaft measures approximately 15 cm in length and 3.5 cm in width. The instrument's handle is rigidly attached to the shaft and measures approximately 10 cm in length. The external housing of the device consists of high impact plastic that surrounds its main internal components. The major external components of the device consist of the instrument's shaft, handle, force adjustment switch, trigger, preload control nose, stylus and power cord. Three types of interchangeable stainless steel stylus' attach to the preload control nose which make contact with the patient by means of a neoprene rubber end. The major internal components of the device consist of a circuit board, power supply, internal thrust element, solenoid, internal spring. Both external and internal views of the device are shown in Figure 1. Stylus specifications are shown in Figure 2, illustrating the three kinds of stylus', a single stylus, and two double contact stylus' that allows for dual contact to each side of the spine simultaneously. These styluses have been designed for appropriate anatomical contact with the spine.

The instrument is manually triggered by the operator and contains a safety mechanism consisting of a triggering mechanism that does not allow for activation of the device unless the preload control spring is maximally compressed. In this manner, the clinician (operator) is able to test the patient's tolerance to contact prior to the instrument being able to be activated. The device is equipped with a force adjustment switch which allows for control of force produced by the instrument, high, medium, and low, representing transmitted peak forces of 265 N, 150 N, and 50 N respectively. Peak forces for all three settings are delivered in less than 5 ms.

The device is operated in the following manner. After locating the target area to be treated the rubber end of the stylus makes contact with the treatment location. An approximate 15 N of preload force compresses the spring allowing for activation of the instrument's trigger mechanism. The operator is then able to manually trigger the device to deliver a single thrust ranging from 50 – 265 N depending on the force setting used.

Substantial Equivalence Comparison:
Impulse™ (aka Neuromechanical™, aka CBP®) Adjusting Instrument is substantially equivalent to other FDA registered predicate hand-held chiropractic adjusting instruments. Specifically, Impulse™ (aka Neuromechanical™, aka CBP®) Adjusting Instrument has the same intended use, similar technological characteristics, and similar force-time profiles as predicate devices. The current device, perhaps, is most similar in structure and function to the *Harrison Hand Held Adjusting Instrument* (K010851). Both hand-held adjusting instruments generate the force to protrude the stylus a controlled distance by means of electrical power that transiently charges a solenoid. The current device, however, has several noteworthy technological characteristics that are similar to predicate devices. Therefore, Table 1 has been prepared to provide a comparison of technological characteristics of the the current device and predicate devices.

Table 1. Substantial equivalence comparison for the current device (*), the Harrison Hand Held Device (K010851), Arthrostim (K930431), Activator II (K973506), and Activator III (K003185).

Feature	Impulse*	Harrison	Arthrostim	Activator II	Activator III
Intended use is chiropractic adjustment of the spine?	Yes	Yes	Yes	Yes	Yes
Hand-held adjusting device?	Yes	Yes	Yes	Yes	Yes
Manually activated thrust?	Yes	Yes	Yes	Yes	Yes
Single thrust per activation?	Yes	Yes	No	Yes	Yes
Thrust force delivered from spring energy?	No	No	No	Yes	Yes
Thrust force delivered from powered solenoid activation?	Yes	Yes	Yes	No	No
Adjustable force transmission	Yes	Yes	Yes	Yes	Yes
Preload control spring	Yes	No	No	No	Yes
Rubber contact end on stylus	Yes	Yes	Yes	Yes	Yes

Force Transmission Comparison Among Chiropractic Adjusting Devices

The force of the current device (*Impulse™ Adjusting Instrument*) was compared to the *Harrison Hand Held Adjusting Instrument* (K010851), and the *Activator® II Adjusting Instrument* (K973506) in a laboratory setting. Ten thrusts were delivered into a load cell (2200 N quartz force ring, PCB model 201A03, PCB Piezotronics, Buffalo, NY[1]) mounted to a table top for each of three force settings for each of the three devices. Collectively, ninety trials were performed, thirty trials with each device consisting of ten trials at each of the three force settings.

Figure 3 provides a comparison of force transmission among the three devices for each of the three force settings. The *Impulse™* device was found to produce an average peak force of 55.8 N, 150.5 N, and 254.4 N respectively (pulse duration < 5 ms) for each of the three force settings that the device allows. As noted in Figure 3, these forces are very similar to the *Activator® II*, and the *Harrison Hand-Held Adjusting Instrument*. The results of this experiment clearly demonstrate that the peak forces transmitted with the current device are of similar magnitude (or lower) to predicate devices and therefore does not raise any new safety or efficacy issues.

Figure 1. External view (left) and internal view (right) of the Impulse™ (aka Neuromechanical™ aka CBP®) Adjusting Instrument.

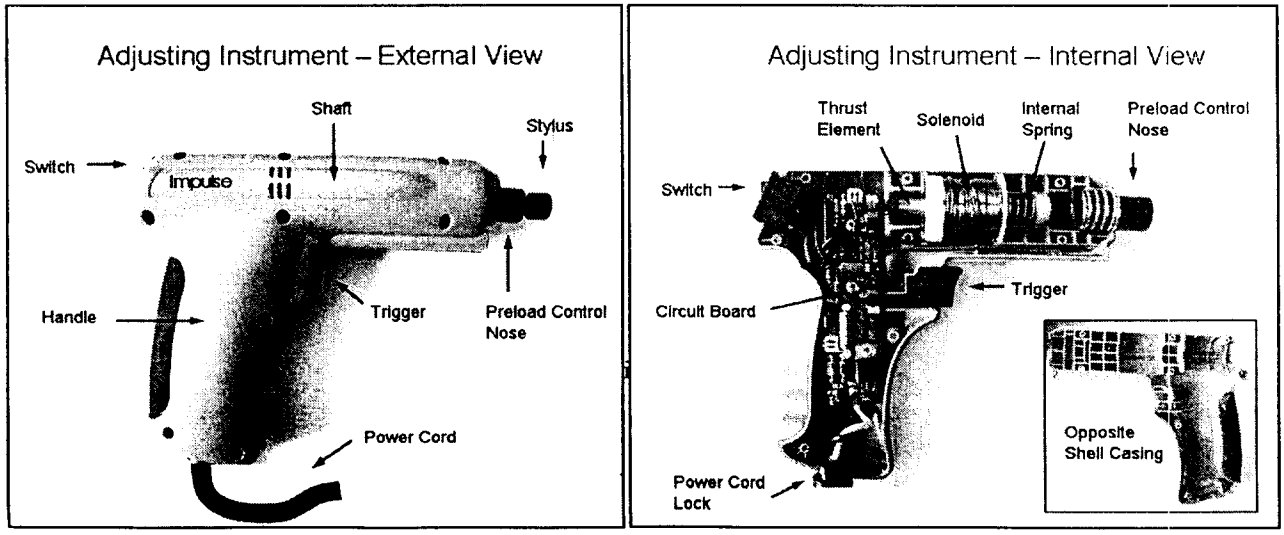


Figure 2. Measurements of the adjusting instrument (left) and stylus attachments (right).

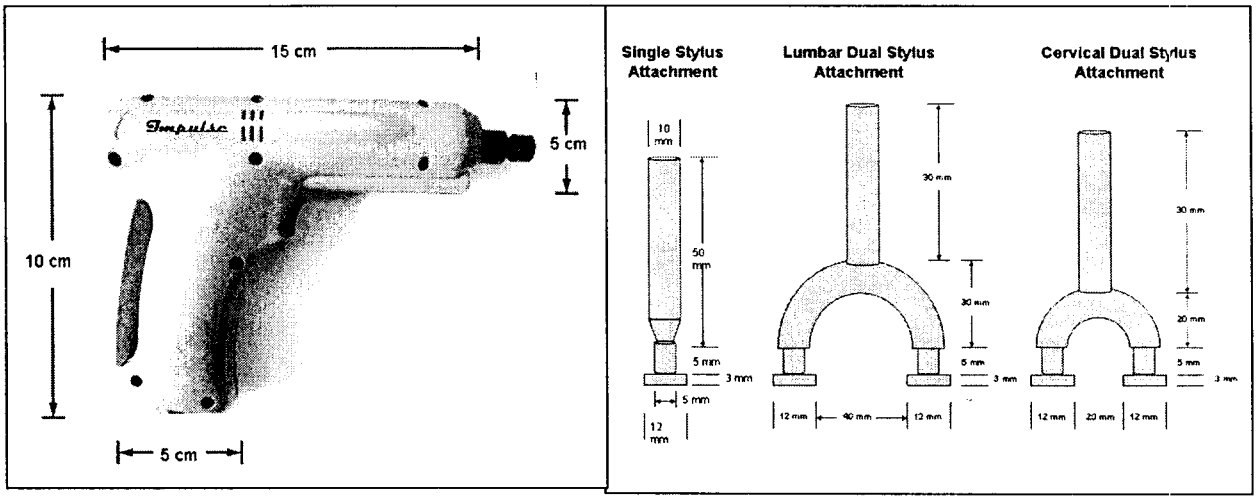
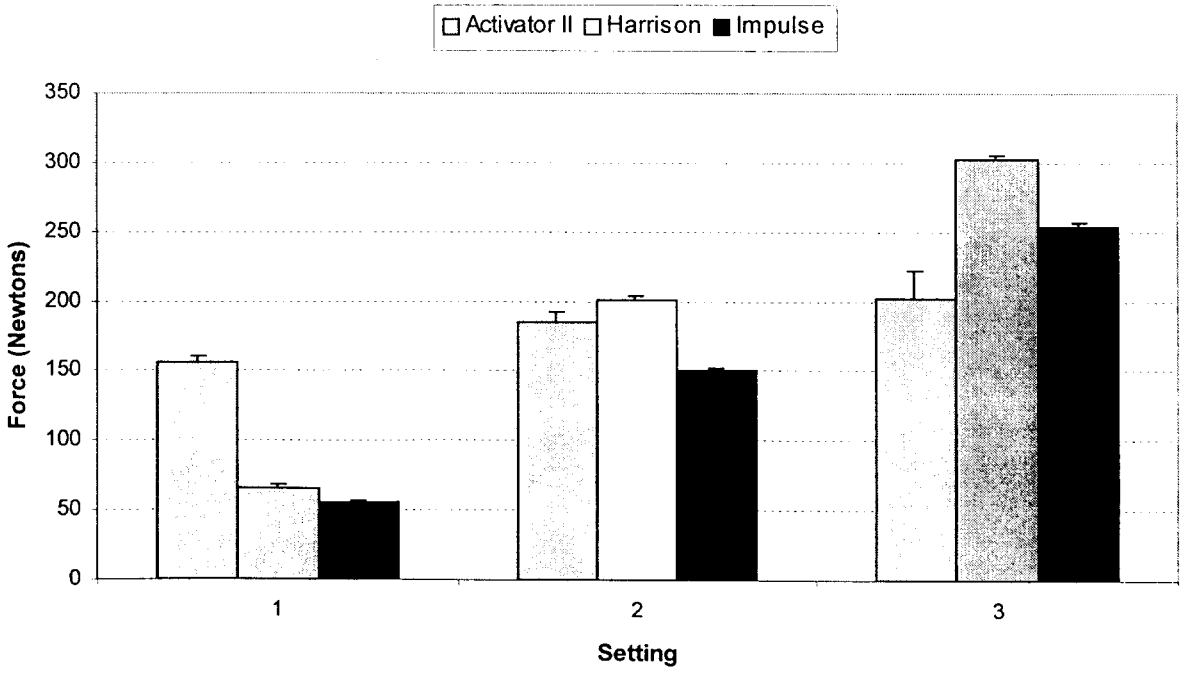


Figure 3. The current device, Impulse™ (aka Neuromechanical™ aka CBP®) Adjusting Instrument was compared to two other FDA registered hand-held chiropractic adjusting devices, the Harrison Hand-Held Adjusting Instrument and the Activator® II Adjusting Instrument. Ten trials were performed at each of three force settings. Error bars represent the standard deviations.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 3 2003

Christopher J. Colloca, D.C.
President
Neuromechanical Innovations, LLC
11011 S 48th Street, Suite 205
Phoenix, Arizona 85044

Re: K023462
Trade Name: Impulse – Adjusting Instrument, aka (also known as) CBP Adjusting Instrument, and aka Neuromechanical Adjusting Instrument
Regulatory Class: Unclassified
Product Code: LXM
Dated: June 3, 2002
Received: October 15, 2002

Dear Dr. Colloca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

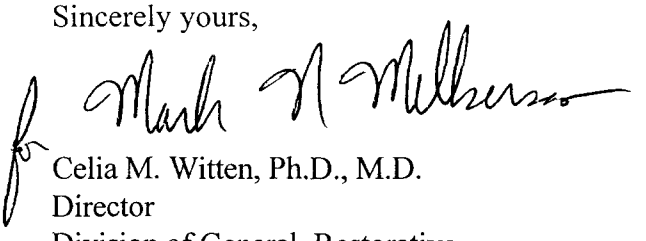
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K023462

Applicant: Neuromechanical Innovations, LLC
11011 S. 48th St., Suite 205
Phoenix, AZ 85044

Contact: Christopher J. Colloca, D.C.
Telephone: 480-893-2400
Facsimile: 480-893-2412

Device Name(s): Impulse™ Adjusting Instrument
Neuromechancial™ Adjusting Instrument
CBP® Adjusting Instrument

Indications For Use:

Impulse™ (aka Neuromechanical™, aka CBP®) Adjusting Instrument is for adjustment, mobilization, or manipulation of the musculoskeletal joints of the spine and/or extremities by a licensed health care professional. The device is for external use only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR (Per 21 CFR 801.109) Over-the-Counter-Use _____

for Mark N. Milhoan
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023462